



AUDIT REPORT FOR SWEDEN

SEPTEMBER 7 THROUGH 15, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Sweden's meat inspection system (NFA) from September 7 –15, 2000. Two establishments certified for export to the United States were audited. One was a slaughter establishment and the other was a warehouse/freezer facility.

The last on-site audit of Sweden's inspection system was conducted in September 1999. Two establishments 206 and 215 were audited: one was acceptable, and the other was evaluated as acceptable re-review. Deficiencies in these establishments pertained to:

1. Insanitary storage of non-meat ingredients in establishments.
2. Inadequate pre-operational cleaning of some processing equipment.
3. Insects in exposed-product areas.
4. Neglected maintenance of overhead structures.
5. Product contact equipment not stored in sanitary manner.
6. Inadequate documentation of corrective actions and preventive measures for Sanitation Standards and Operational Procedures (SSOP).
7. Residues sample not analyzed within required turn around time.
8. A laboratory check sample program did not meet FSIS requirements.
9. Lack of adequate laboratory controls regarding standards books and expiration dates of analyses.

At the time of this audit, both of these establishments (206 and 215) had voluntarily withdrawn their export eligibility due to organizational restructuring.

The auditor, during this audit, verified that in establishments visited, similar deficiencies were not present.

As of the end of August 2000, Sweden exported 131,100 pounds of fresh/frozen product to the United States. On port of entry reinspection 22,619 pounds were rejected due to missing shipping marks, and processing defects.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with various Sweden meat inspection officials to discuss oversight programs and practices, including enforcement

activities. The second entailed discussions and audit of selected inspection system control documents maintained at the headquarters. The third included on-site visits to the two establishments. The fourth was a visit to three laboratories performing analytical testing of samples for the national residue and microbiological monitoring program, testing *Salmonella* species, and testing generic *Escherichia coli* (*E. coli*).

Program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Sweden's inspection system was assessed by evaluating these five risk areas.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary:

SSOP records lacked documentation on corrective and preventive actions taken in the establishments 80 and 455 visited.

In establishment 80, the HACCP written plans did not list the critical limits (CL's), and procedures to record actual values and observations to monitor each of the critical control point to ensure compliance with the critical limits. The establishment records did not document corrective actions taken in response to a deviation to bring the critical control points (CCPs) under control, to establish measures to prevent recurrence, and to prevent distribution of product adulterated as a result of the deviation.

Generic *E. coli* samples were not being collected from the ham area. The establishment did not record or use process control technique (charting or plotting the results overtime) to determine what variation in test results was within normal limits. The normal limits for the sponging technique were not established.

Salmonella species testing was being done according to FSIS equivalence determined procedures. Investigation on animals/farms and other action were taken according to the national *Salmonella* control program. However, there was no stipulation to stop operations in an

establishment where violations continued to exist. The official (in-plant) inspectors were not trained in Pathogen Reduction (PR) and HACCP. The inspection service did not routinely monitor and/or record establishment system's noncompliance of the PR/HACCP.

In establishment 80, porcine carcasses were not washed before making opening cuts; mesenteric lymph nodes were not being palpated; and the dead on arrival (DOA) carcasses and condemned or inedible product were not denatured before shipping off the establishment premises.

Inadequate inspection system control or deficiency of execution by the in-plant inspectors was not documented. The inspector's performance was not being evaluated or rated.

The residue testing laboratories were acceptable. However, no changes had been made in the laboratory quality assurance standards regarding analytical turn-around time, and inter-and intralaboratory check sampling procedures. The mercury and arsenic trace elements residues in meat were also not being tested.

Entrance Meeting

On September 7, an entrance meeting was held at the NFA offices, and was attended by Dr. Lars Plym Forshell, Assistant Chief Veterinary Officer; Drs. Christer Ohlsen, Peter Wasenberg, Senior Veterinary Officers (Filed Operations Coordinators); Dr. Eva Ortenberg, Veterinary Officer (*Salmonella* Testing Program Coordinator); Dr. Bengt-Goran Osterdahl, Head of Chemistry Division; Ms Ingrid Nordlander, Executive Officer; and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS, Field Operations. Topics of discussion included:

1. Audit itinerary.
2. Use of nutritional or geographic claim labels.
3. Failure to develop or effectively implement SSOP.
4. Effective implementation of sanitation, facilities and equipment performance standards.
5. Deficiencies in conducting in laboratory quality assurance program.
6. Performances deficiencies in conducting proper postmortem inspection procedures.
7. Oversight and verification of PR/HACCP.
8. FSIS policy on 'listing and delisting' of establishments.

Sweden's inspection system officials stated that these deficiencies had been properly addressed, and effective control measures had been taken to prevent recurrence.

Headquarters Audit

In July 2000, Sweden reorganized the National Food Administration (NFA), under which the Ministry of Agriculture regulates matters concerning food and drinking water. The Director-General assisted by the Deputy Director heads five departments: research and development, food standards (regulations), food control, information and nutrition, and administration. The Food Control Department is responsible for all activities involving the implementation of regulations,

and is the responsible food control authority. It has three Divisions - Meat Inspection Division, Inspection and Coordination Division, and Implementation Division. Ms. Ossa Breiding is Chief of the Department.

Dr. Margreta Widely is the Chief Veterinarian of the Meat Inspection Division. The Meat Inspection Division carries out inspection and control of slaughter and other meat product establishments. In collaboration with other divisions, it also develops control activities. The Inspection and Coordination Division directs control and evaluates the municipal food inspection activities (including drinking water). The Implementation Division handles questions on permits, notifications, and application for exemption and certificates.

To gain an accurate overview of the effectiveness of inspection controls, FSIS auditor requested that the audits of the individual establishments be lead by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditor conducted a review of the inspection system documents. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Epidemiology and zoonotic trends in Sweden.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Sweden as eligible to export meat product to the United States were full-time or part-time NFA employees receiving no remuneration directly from either industry or establishment personnel.

In the establishments visited (80 and 455), the official inspectors observe and visually verify the performance of establishments to prepare and distribute safe and wholesome product according to the domestic and importing country requirements. Written observation or results are not documented. Dr. Margreta Widdel is the direct supervisor of about 90 in-plant inspectors, and six senior veterinary officers (Internal Coordinators). The Internal Coordinators, at least once a year, conduct audit of about 240 establishments, and focus on periodically targeted areas for in-

depth review. The inspector's performance is not evaluated or rated. There appears to be no consequence for neglect of duty or deficiency of execution of responsibility. It was stated that the inspectors were traditionally honor-bound and trusted to perform their duties, and that the focus was on the performance of establishments, which were inherently responsible for compliance with the rules, quality assurance, and product safety.

Each establishment was in-depth audited by the non-supervisory 'internal coordinators' program officials, at least annually, and monthly visit the NFA certified establishments as eligible to export to the United States. They identify in-plant operational deficiencies and/or non-compliance, and notify the inspector-in-charge and the establishment. The inspection staff performance or effectiveness of inspection control is not evaluated, and/or documented.

Establishment Audits

Two establishments (80 and 455) were certified to export meat products to the United States at the time this audit was conducted. Both were visited for on-site audits. In these establishments, both NFA inspection system controls and establishment system controls were in place and/or a number of deficiencies were noted during the audits. These deficiencies have been described in the report.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Inter-laboratory quality assurance procedures, including sample handling.
3. Methodology.

On September 8, 2000, the auditor visited National Food Administration Laboratory (Veterinary Drug Residues Laboratory) in Uppsala; on September 11 the National Veterinary Institute (SVA) including the National Zoonosis Center; on September 14 visited one of the private (accredited) laboratory contracted by NFA to test residues and micro-organisms; and on September 13 visited one of the privately-establishment (80) owned laboratory testing generic *E. coli*. The deviations noted during the previous FSIS audit in September 1999 had been corrected.

Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. It was noted that mercury and arsenic residue elements were not being tested. It was stated that years of testing revealed insignificant public health or animal health hazards, therefore testing for mercury and arsenic had been discontinued since 1996 and 1991, respectively. NFA officials stated the testing was

discontinued due to continued negative results. The auditor requested NFA to send the data and justification for seeking exemption to IPD, and meanwhile continue testing until IPD determines the exemption status. It was also stated that they did not intend to do so at the present, but would reconsider it during next year's residue testing plan. They would also seek exception for testing these elements.

It was stated that testing for carbadox, benzimidazol and levamisole would be started when the methods had been validated.

Establishment Operations by Establishment Number

The following operations were being conducted in the establishments conducted:

Pork slaughter and cut up/boning (Est. 80)
Freezer/warehouse and packaging (Est. 451)

SANITATION CONTROLS

Based on the on-site audit, generally the monitoring and verification of inspection system or establishments was inadequate and/or inconsistent with the requirements. No documentation for identified deficiencies or the corrective actions taken by the establishment or the inspection service for product contamination on re-inspection was available to assure that effective measures were being taken by the establishment to produce and distribute wholesome, unadulterated, and properly labeled products.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

Generally, the SSOPs met the basic regulatory requirements. However, the SSOP records lacked documentation on corrective and preventive actions taken in the two establishments 80 and 455 visited. The daily pre-operational and operational deficiencies when observed were checked off, but not described.

ANIMAL DISEASE CONTROLS

During the Swedish Veterinary Institute (SVI) visit, the auditor reviewed records on Swedish sources of epidemiology, and the zoonotic infections recorded in Sweden during 1999. It was stated that Sweden was free of tuberculosis (animals and humans), brucellosis (animals and humans), foot and mouth disease, rinderpest, vesicular diseases, cysticercosis, and rabies. Also

there was insignificant incidence of *Salmonella*, *Trichinella spiralis*, *Thermophilic Campylobacter*, *Listeria monocytogenes*, *Toxoplasma gondii*, *Yersinia enterocolitica*, and *Echinococcosis*. However, 11 cases were confirmed for *Verocytotoxic E. coli* 0157 in animals, and 33 cases in 111 food samples, and incidence in humans was insignificant.

No cases were reported for BSE.

The author also determined that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) requirements for animal health and epidemiological status were being met.

RESIDUE CONTROLS

Sweden's National Residue testing Plan for 200 was being followed, and was on schedule. It was stated that Finland's national residue program had been developed and executed according to national accreditation body's standard laboratory quality assurance plan, and was in accordance with European Union's directives and approved plan. Therefore changes in quality assurance standards regarding analytical methods, analytical turn-around time, inter- and intralaboratory check samples procedures program (as requested by FSIS auditor during the previous audit) were not likely to be made unless European Union's relevant body directed or acted on it.

HACCP Implementation

All establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

However, in establishment 80, the HACCP written plans did not (1) list the critical limits (CL) that must be met at each of the critical control point, and (2) the procedures to record actual values and observations that would be used to monitor each of the critical control points (CCP) to ensure compliance with the CL: only visual observation once a day at each of 5-CCP was listed. The establishment's records did not document corrective actions taken in response to a deviation from the critical limits, including procedure(s) to identify and eliminate the cause of deviation, to bring the CCP under control, to establish measures to prevent recurrence, and to prevent distribution of product adulterated as a result of the deviation.

The official (in-plant) inspectors were not trained in Pathogen Reduction (PR) and HACCP.

Testing for generic *E. coli*

Two establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

However, the establishment was not conducting the generic *E. coli* sampling. Official inspectors collected samples from two sites instead of three. The establishment did not record or use process control technique (charting or plotting the results overtime) to determine what variation in test results was within normal limits. The normal limits were not established. The fecal contamination control program did not meet the requirements.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below Sweden's inspection system controls ante-and post-mortem inspection (swine) and dispositions, and performs monthly in-depth reviews of U.S.-certified establishments. The establishment's system conducts boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, the importation of only eligible livestock from other countries (i.e., only from eligible meat product from other countries for further processing) were in place and effective ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were in place for security items, shipment security, and products entering the establishment from outside sources.

However it was noted that the inspection system lacked employee performance standards or clearly defined supervisory function pertaining to inspection system controls. Inspector-in-charge executed inspection controls (domestic or international), as he/she deemed fit. There were six senior veterinary officers assigned to inspect about 240 establishment annually, and provide 'guidance' to the industry and the inspector. Their observations made by these officials were advisory and were not binding.

Additionally, the auditor also determined that:

- The inspectors were not trained in PR/HACCP systems.
- The inspectors did not record any monitoring or observation for compliance of requirements other than antemortem and postmortem inspection.
- In establishment 80, the carcasses were not being washed before making opening cuts on carcasses; the mesenteric lymph nodes were not being palpated; and the dead on arrival (DOA) carcasses, condemned/inedible products were not denatured before shipping off the premises.

Testing for *Salmonella* Species

One establishment (80) audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Sweden has adopted an equivalent *Salmonella* testing program, which had been in place for over several years. The *Salmonella* testing plan is developed and monitored by the SVA's epidemiology (Zoocenter) section, and microbiology sections of National Veterinary Institute. The sampling is done by the NFA inspectors according to FSIS evaluated procedures for equivalence, and tested in national accredited regional and private laboratories.

Species Verification Testing

At the time of this audit, Sweden was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States. Required monthly establishment's audits were being conducted.

Enforcement Activities

Latest FSIS Quarterly Regulation and Enforcement Report (January – March 2000) was presented to NFA officials. It was stated that information requested by FSIS International Policy Division had been sent in July 2000.

Exit Meeting

An exit meeting was conducted in Uppsala on September 15, 2000. The participants were Drs. Margreta Widell, Anders Ackberg, Christer Ohlsen, Peter Wasenberg, Barbero Ljung, Paulo Krishka, Eva Ortenberg, and Ms Bengt-Goran Osterahl, and Dr. Hussain Magsi, FSIS, Field Operations.

The observations made during the audit and stated above were discussed. NFA officials stated that immediate administrative measures had been initiated to correct deficiencies noted during the audit for not washing of carcasses prior to opening cuts, not palpating mesenteric lymph

nodes not denaturing/decharacterizing condemned or inedible product and dead on arrival (DOA) carcasses before removal from the establishment premises, inedible product, and deficiencies in SSOPs, deviations in generic *E. coli* sampling procedures, and HACCP plans implementation.

It was also stated that HACCP training and correlation for in-plant inspectors to seek effective inspection controls would be started during this week, however, the establishments were charged user-fees, and due to economic reasons, and according to European Union authorized procedures, continuous inspection of all establishments could not be resolved at the present time.

CONCLUSION

The inspection system was deficient in ensuring continued effective monitoring and control by the official in-plant inspectors under conditions equivalent to those FSIS requires in domestic establishments. These deficiencies require prompt follow-up with Swedish officials.

(signed) Hussain Magsi, DVM, MS

Hussain Magsi, DVM, MS
International Audit Staff Officer

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
- H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1. Written program addressed	2. Pre-op sanitation addressed	3. Operational Sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible individual Identified	7. Documentation done daily	8. Dated and signed
80	√	*	*	√	√	√	√	√
455	√	*	*	√	√	√	√	√

* Corrective and preventative actions were described in the written plans. Deficiencies noted, and corrective actions and preventative actions taken were not described in daily observations.

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
1. The HACCP plan was validated using multiple monitoring results.
2. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1. Flow diagram	2. Hazard analysis done	3. All hazards identified	4. Use and users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring specified	8. Corrective actions described	9. Plan validated	10. Adequate verification procedures	11. Adequate documentation	12. Dated and signed
80	√	√	√	√	√	√	*	*	√	√	*	√

* Critical limits were not specific as to the desired limits, and the frequency of monitoring critical limits was inadequate or ineffective. Written plans did describe deficiencies noted, corrective actions taken or preventive measures taken.

Data collection instruments for *E. coli* testing

Following information was collected.

1. The establishment has a written procedure for testing for generic *Enterobacteriaceae*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. No.	1. Writ-ten procedure	2. Sample collector designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr.
80	√	√	√	√	√	*	√	√	No**	√

* Ham area was not sampled.

** Criteria for verifying process control using surface-sampling procedures was not established, and statistical process control techniques were not developed to evaluate test results.

Data Collection instruments for *Salmonella* spp. Testing

Establishment 80 was evaluated to determine if the *Salmonella* species performance standards requirement met U.S. requirement criteria approved for equivalence.

The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. Number	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative Est. - stop operations
80	* √	√	N/A	√	√	**

** Investigation on animals/farms, and other action are taken according to the national *Salmonella* control program, butt here is no stipulation to stop operations in an establishment where violations continue to exist.